

Toxicological Information- und Data Network - A European Challenge?

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RISK ASSESSMENT ON THE BASIS OF POISON CENTRE DATA

Dr M. MATHIEU-NOLF

Historically, clinical toxicology / poison information services and regulatory / risk assessment have existed in two parallel worlds and have developed as separate disciplines sharing the common objective of protecting human health.

Regulatory toxicologists are assessing substances in order to prevent harmfulness of chemicals for human during occupation, as consumer and to protect environment. Their work includes a hazard assessment of the potential effects of the chemical (identification of human effects...) and an assessment of the likely exposures to the chemical (circumstances of use, population at risk...).

For example, one important information needed for risk assessment work is the No-Observed Adverse Effect Level (NOAEL). Data used come mainly from standardized animal studies. One of their major challenge is how to act with the uncertainty of using animal model for human health effects, and how to evaluate the circumstance of human exposure at different ages (child, ...) and in different uses.

Poison centres clinical toxicologists are assessing the risk of poisoning after acute or chronic exposure of individuals, in order to evaluate the prognosis, to give advise to treat patient and to prevent complications. Poison centres in E.U. have access to product formulations and are collecting information of cases. Sometimes, they have to deal with lack of information concerning the potential toxic effects for human (example : chemical industrial accident, new product) and are using information from animal studies and similar substances.

These two disciplines have developed strategies to act in the absence of information on the effects and potential for exposure.

The need to use Poison centres experience in risk assessment

In France, the need of Poison Centres involved in the national risk assessment process has been identified some years ago. In 1996, the french law has defined the role of poison centres in the country and set up the national toxicovigilance network. In 1997, in France, the Ministry of Health / Direction Générale de la Santé, has involved several poison centres clinical toxicologists in the process of regulatory risk assessment of existing substances following the european regulation EC793/93 on regulation and control of existing chemical substances. So, the role of poison centre has been dramatically expended and includes the continuous surveillance of human exposures, the risk assessment of health effects of chemicals in humans and the expertise to authorities after environmental pollution indoors and outdoors.

The Lille Poison centre programme.

As an example, the Lille Poison Centre has developed a surveillance programme of human exposures to chemicals.

For this purpose the Lille PC has set up a network of case records collection in several toxicovigilance collaborating hospitals in the region. The case toxicovigilance data base includes cases from Poison Information Unit, the adult and pediatric emergency department in differents hospitals and forensic Institutes. All cases are followed by phone by the toxicovigilance Unit and the overall clinical course is evaluated and the P.S.S. is scored for each case. These toxicovigilance data base linked to the product data base may be used :

- to alert the Ministry of Health and Consumption Authorities when a high risk is identified,
- to identify priorities in prevention and to evaluate prevention programmes.

In our experience, there is a great challenge for Poison Centres to contribute to the regulatory risk assessment process by providing their knowledge on health effects on humans of chemicals in their daily life. This could include human epidemiological data, clinical effects after accidental or

occupational exposures, information on acute toxicity (cutaneous, ocular, respiratory) and sensitization (cutaneous, respiratory). In our opinion, the main use of PC data for risk assessment seems to be in the hazard assessment by identifying/confirming the toxicity of chemicals predicted by animal studies (target organs), dose or concentration for critical effect, for NAOEL, and in the likely assessment by identifying the circumstance of exposure (normal/over exposure/accident) and the population at risk, and in the process of identifying priorities in prevention against chemicals for humans by producing information on frequency, and severity, and distribution of harmful chemicals in products.

As an example of feasibility, we reported in this presentation the results of our data analysed in this perspective.

Conclusion

But PC cannot solve any of the existing problems and difficulties still exist to obtain useful human data (uncontrolled variables, incomplete exposure estimations, differences in responses between individuals...).

So, PC have a key role to play in the prevention strategies to protect human health from chemicals but they should focus on the quality and adequacy of the data collected to allow their use for risk assessment.